REMARKS

This is in response to the Office Action mailed September 8, 2006. Claims 47-54 and 56-59 read on the elected species SEQ ID NO: 2, and are pending in the application. Applicants herewith cancel claims 51 and 57, without prejudice or disclaimer. With the entry of this amendment, claims 47-50, 52-54, 56, and 58-59 will be active in this case.

I. Objections

The Examiner holds that the listing of references in the specification is not a proper information disclosure statement. 37 C.F.R. § 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." The Examiner concludes that unless the references have been cited by the Examiner on form PTO-892, they have not been considered.

The Examiner further explains what type of references can be incorporated into the specification.

In response, Applicants thank the Examiner for clarifying this issue. Applicants further draw the Examiner's attention to the Information Disclosure Statements filed December 3, 2003, and October 12, 2005. Applicants herewith submit a third Information Disclosure Statement submitting references that disclose background information within the field of the invention. Applicants request the Examiner to acknowledge consideration of such references in due course.

II. Claim Rejection under 35 U.S.C. § 112

The Examiner rejects claims 47-52, 54 and 56-59 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. According to the Examiner, the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at

the time the application was filed, had possession of the claims invention. This is a new matter rejection.

The Examiner explains that the amendatory material that is not supported by the specification and claims as originally filed is as follows:

- A nucleic acid molecule encoding **a** CEA molecule consisting of an amino acid sequence that is one of SEQ ID NO: 2-5, vector, host cell and kit thereof (claim 47 et seq.);
- A composition comprising the nucleic acid molecule of claim 47.

In response, applicants traverse this rejection for reasons already in the record and in view of applicable comments below. However, in order to advance prosecution, applicants have amended claim 47 to simply recite a nucleic acid molecule encoding an amino acid sequence consisting of one of SEQ ID NO: 2-5. Support for this subject matter can be found in the specification at page 6, lines 22-31 and page 7, line 30 - 32 and at page 19, line 18 to page 20, line 16. Thus, no new matter is added with this amendment. In the amendment, Applicants eliminate reference to "***a*** CEA molecule" and thereby render the Examiner's objection moot. Applicants further assert that this amendment overcomes rejections of claims that depend from claim 47.

The Examiner rejects claims 47-54 and 56-59 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. According to the Examiner, the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner clarifies that this is a written description rejection.

The Examiner states that in the instant case, the specification does not convey to the artisan that Applicants had possession at the time of invention of the claimed nucleic acid molecule, vector, host cell and kit thereof recited in the instant claims 47-52, 56-58, kit comprising a vector comprising a nucleic acid comprising the nucleic acid sequence

encoding SEQ ID NO: 2 recited in instant claim 54, and a kit comprising an agonist peptide and a vector comprising a gene encoding CEA or a recombinantly produced CEA protein recited in instant claim 53.

The Examiner explains that the instant claims encompass a nucleic acid molecule encoding a CEA molecule consisting of an amino acid sequence that is one of SEQ ID NO: 2-5, i.e., a nucleic acid molecule encoding a *fragment* of one of SEQ ID NO: 2-5, vector, host cell and kit thereof (claims 47-52, 56-58), kit comprising a vector comprising a nucleic acid *comprising* the nucleic acid sequence encoding SEQ ID NO: 2 (claim 54), and a kit comprising any agonist peptide, not necessarily from CEA, and a vector comprising a gene encoding CEA *or a recombinantly produced CEA protein* (claim 53). The Examiner concludes that there is insufficient disclosure in the specification for such an invention.

The Examiner further states that as to the issue of *comprises*, the specification does not disclose flanking sequences for SEQ ID NO: 2-5, nor what nucleic acid sequences would encode them. The specification likewise does not disclose nucleic acid molecules that encode a fragment of one of SEQ ID NO: 2-5. The specification does not disclose the definition of 'a CEA protein.' The Examiner states that the specification discloses that the human CEA is a 180 kDa glycoprotein expressed on the majority of colon, rectal, stomach and pancreatic tumors, some breast carcinomas, and a majority of lung carcinomas, in fetal gut tissue and to a lesser extent on normal colon epithelium.

In response, Applicants traverse this rejection for reasons already of record. Applicants further traverse this rejection because the Examiner's arguments are confusing. Namely, it is not clear why the Examiner interprets the claims as encompassing fragments of the recited SEQ ID NO's. The rejected claims do not recite fragments. Rejected claim 47 does not recite "comprising." But even if claim 47 did recite "comprising," the term "comprising" doesn't result in an interpretation that includes fragments. "Comprising" means that the invention must contain the recited elements but could also include other elements that are not recited. "Comprising" does not traditionally mean that part of what is claimed could be lacking. It also is not clear why the term "***a*** CEA molecule," which was recited in the rejected claim, is so objectionable. All of the recited peptides derive from the

CEA molecule, that is the 180 kDa molecule that the Examiner has acknowledged. The specification clearly describes this and how the recited peptides could be produced either by synthesis or by recombinant methods. These methods were well-known and accepted at the time of the invention. It is simply not clear why the Examiner does not think a skilled artisan would think applicants were in possession of this invention at the time of the invention.

However, in order to advance prosecution, applicants have amended claim 47. Amended claim 47 does not recite "***a*** CEA molecule," which the Examiner has highlighted as being objectionable. Rather, amended claim 47 recites a nucleic acid molecule that encodes an amino acid sequence that consists of a sequence selected from the group consisting of SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4 and SEQ ID NO: 5. The language is clear, concise and fully described and enabled by the specification, as pointed out above.

The Examiner further rejects claims 47-54 and 56 under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner explains that the specification has not enabled the breadth of the claimed invention because the claims encompass a nucleic acid molecule encoding a CEA molecule consisting of an amino acid sequence that is one of SEQ ID NO: 2-5, *i.e.,* a nucleic acid molecule encoding a *fragment* of one of SEQ ID NO: 2-5, vector, host cell and kit thereof (claims 47-52, 56-58), a kit comprising a vector comprising a nucleic acid *comprising* the nucleic acid sequence encoding SEQ ID NO: 2 (claim 54), and a kit comprising any agonist peptide, not necessarily from CEA, and a vector comprising a gene encoding CEA *or a recombinantly produced CEA protein* (claim 53). According to the Examiner, the state of the art is such that it is unpredictable in the absence of appropriate evidence whether the claimed nucleic acid molecules, vectors, host cells and kit thereof can be made and/or used. The Examiner further opined that there is insufficient guidance in the specification as to how to make and/or use instant invention. Undue experimentation would be required of one skilled in the art to practice the instant invention, citing In re Wands 8 USPQ2d 1400 (CAFC 1988).

In response, Applicants traverse this rejection. Applicants believe that most of the Examiner's objections have been addressed above. However, applicants also amend herewith claim 53 to clarify that the kit of the invention comprises a "CEA" agonist peptide. Support for this amendment can be found at page 7, lines 10-14. The agonist peptides referred to in this excerpt are the CEA agonist peptides described throughout the specification. Additionally, applicants amend claim 54 to remove "vector comprises a nucleic acid comprising the nucleic acid sequence encoding...." Amended claim 54 now simply further clarifies that the agonist peptide of claim 53 is SEQ ID NO: 2. In view of these amendments, applicants assert that the Examiner's rejection for lack of enablement is moot. Withdrawal thereof is therefore respectfully requested.

III. Claim Rejection under 35 U.S.C. § 102

The Examiner states that for the purpose of prior art rejections, the filing date of the instant claims 47-52 and 56-59 is deemed to be the filing date of the instant application, *i.e.* 12/3/03, as the parent applications do not support the claimed limitations of the instant application as enunciated at item #6 of the present Office Action. The Examiner further states that for the purpose of prior art rejections, the filing date of the instant claim 53 is deemed to be the filing date of the 60/061,589 parent application, *i.e.,* 10/10/97. Applicants will address these conclusions below in connection with the various prior art rejections.

The Examiner rejects claims 47-49, 52, 54 and 57-59 under 35 U.S.C. § 102(b) as being anticipated by WO 00/34494. WO 00/34494 published on June 15, 2000. The claims as presently amended are entitled to the benefit of priority of the parent application, 60/061,589, which is October 10, 1997. Specifically, the parent application describes SEQ ID Nos: 2-5 and nucleic acid molecules encoding them and related vectors and host cells, at page 5, line 20 to page 6, line 21; page 15, line 12 to page 16, line 32 and in the claims. Because the parent application fully supports the amended claims, applicants respectfully request the Examiner to grant the claims the benefit of the priority date, thereby removing WO 00/34494 as a prior art reference.

The Examiner also rejects claims 47-49, 52, 54 and 57-59 under 35 U.S.C. § 102(e) as being anticipated by US 2004/0019195 A1. Applicants again respond by asking the Examiner to reconsider this rejection as it applies to the amended claims. Because the amended claims are entitled to the benefit of the earliest priority date, the cited reference is not prior art. Withdrawal of this rejection is respectfully requested.

The Examiner further rejects claims 47-49, 52, 54 and 57-59 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,969,609 B1. U.S. Patent No. 6,969,609 B1 has an effective filing date of December 9, 1998, which is after the filing date to which the presently amended claims should be granted. As such, U.S. Patent No. 6,969,609 B1 should not be prior art against the current claims and withdrawal of this rejection is respectfully requested.

IV. Claim Rejections under 35 U.S.C. § 103

The Examiner rejects claims 47-52, 54 and 56-59 under 35 U.S.C. § 103(a) as being obvious over US 2004/0019195 A1 in view of WO 91/02805 A2. The Examiner further rejects claims 47-52, 54 and 56-59 under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,969,609 B1 in view of WO 91/02805 A2. The Examiner also rejects claims 47-52, 54 and 56-59 under 35 U.S.C. § 103(a) as being obvious over WO 00/34494 A1 in view of WO 91/02805 A2.

In each of the above combinations of references, the Examiner relies upon a primary reference that is not valid prior art against the currently amended claims. Thus, without conceding on the merits of this rejection, applicants assert that the rejections are not proper and respectfully request withdrawal of the same.

V. Claim Rejections under Doctrine of Double Patenting

The Examiner provisionally rejects claims 47-49 and 57-59 under the judicially created doctrine of double patenting over claims 18, 19, 26, 27 and 35 of copending Application No. 10/406,317. According to the Examiner, although the conflicting claims are

not identical, they are not patentably distinct from each other because the vector of instant claims 48 and 49 are nucleic acids that comprise the nucleic acid of instant claim 47, and the vector of '317 is also a nucleic acid that comprises a nucleic acid that comprises a nucleic acid sequence encoding SEQ ID NO: 2 of the instant claims (SEQ ID NO: 24 of '317). Also, although the vector of the '317 claims 18, 19, 26 and 27 also comprise additional coding sequences, the said vector comprises a nucleic acid molecule that encodes SEQ ID NO: 2. Instant claim 49 is included in this rejection because the poxviruses orthopox, avipox, capripox and suipox are obvious variants of vector as evidenced by claims 11 and 14 of '317. Instant claims 58 and 59 are included in this rejection because they are encompassed by the composition recited in claim 35 of '317, and the composition comprising the vector comprises the nucleic acid molecule encoding a tumor antigen of the claim 35 of '317.

Because this is a provisional double patenting rejection and the claims of the present application have been amended, and the conflicting claims have not yet been patented, applicants wish to address this objections when subject matter has been considered allowable.

The Examiner further provisionally rejects claims 50-52, 54 and 56 under the judicially created doctrine of double patenting over claims 18, 19, 26, 27 and 35 of copending Application No. 10/406,317 as applied to claims 47-49 and 57-59 above, and further in view of US 6,319,496 B1 and WO 91/02805 A2.

The Examiner explains that claims 18, 19, 26, 27 and 35 of copending Application No. 10/406,317 do not recite wherein the vector further comprises a nucleotide sequence encoding HLA-A2 and is comprised in a host cell or kit. The Examiner relies upon US 6,319,496 B1, which is said to disclose making suipox, avipox, capripox or orthopox viral vectors comprising a nucleic acid sequence encoding CEA or one of the CAP-1-CAP10 peptides and a host cell comprising said vector, and that HLA-A2 is the restriction element for the CAP1-CAP-10 peptides, and that tumor cells that express HLA-A2 were capable of presenting the peptides (especially column 3 at lines 1-13, column 4 at lines 45-65, abstract). The Examiner also relies upon WO 91/02805 A2, which is said to teach

transfecting tumor cells with a recombinant viral vector construct that directs expression of both a tumor antigen or portion thereof and an MHC protein such as an MHC class I protein that is capable of presenting the tumor antigen or portion thereof in order to stimulate CTL in a subject animal. WO 91/02805 A2 is said to teach that this is advantageous in augmenting antigen presentation in tumor cells that have reduced levels of MHC proteins and a reduced ability to stimulate an immune response (especially Summary of the Invention on pages 5-7 (through line 29)).

The Examiner then concludes that it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have constructed the viral vector of claims 18, 19, 26, 27 and 35 of '317 to further comprise nucleic acid sequence encoding HLA-A2 as per the teaching of WO 91/02805 A2 of making a recombinant viral vector that directs expression of both a tumor antigen or peptide thereof and the MHC class I protein that presents it, and to have transfected host cells as per the disclosure of US 6,319,496 B1 for other CAP antigenic peptides or the teaching of WO 91/02805 A2 for other tumor peptides and to have placed the said vector into a kit.

The Examiner then opines on why one of ordinary skill in the art at the time the invention would have been motivated to do this.

Because this is a provisional double patenting rejection and the present claims are recently amended and the conflicting claims have not yet been patented, applicants wish to respond to this rejection at a later date, when there is allowable subject matter.

The Examiner further states that claims 47-52, 54 and 56-59 are directed to an invention not patentably distinct from claims 18, 19, 26, 27 and 35 of commonly assigned application serial no. 10/406,317, as enunciated at items # 19 and #20 *supra*.

The Examiner states that U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 10/406,317, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. § 103(a) if the commonly

assigned case qualifies as prior art under 35 U.S.C. § 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. § 103(c) and 37 C.F.R. § 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. § 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. § 102(f) or (g), or 35 U.S.C. § 102(e) for applications filed on or after November 29, 1999.

In response, Applicants again request this issue be held in abeyance until the claims in the respective applications, which have always been commonly assigned, are in condition for allowance. A copy of the assignment recordations are attached for each case.

Claim 51 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 16 of U.S. Patent No. 6,969,609 B1 in view of US 6,319,496 B1 and WO 91/02805 A2. In response, applicants herewith cancel claim 51 without prejudice or disclaimer.

The Examiner further rejects claim 51 as being directed to an invention not patentably distinct from claim 16 of commonly assigned US Patent No. 6,969,609 B1 as enunciated at item #18 of this action supra. This rejection is rendered moot in view of the cancellation of claim 51.

Claim 56 is objected to because of the following informality: Claim 56 has two sets of identical claim numbers. Appropriate correction is required. In response, Applicants have amended claim 56.

CONCLUSION

In light of the above amendments and comments, Applicants respectfully request that all rejections and objections be withdrawn and that a timely Notice of Allowance should be issued in this application. Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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